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TITLE: Hot Flashes and Quality of Life Among Breast Cancer Patients

PRINCIPAL INVESTIGATOR: Linda A. Jacobs, Ph.D.

CONTRACTING ORGANIZATION: University of Pennsylvania
Philadelphia, Pennsylvania 19104-6205

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14. ABSTRACT
This prospective study examined hot flashes and quality of life (QOL) in BC patients undergoing initial treatment. The medical and complementary and alternative medicine (CAM) interventions used by patients were also examined. One hundred and ninety-six women were recruited to the study and data for several time-points continues to be collected on women who were recruited to the study 12 months ago in order to complete their 15 and 18 month questionnaires. A limited analysis of data gathered to date is available. Women were assessed for hot flash intensity/frequency, use of medical and CAM interventions, emotional distress, physical and social functioning, and QOL at diagnosis and 6, 9, 12, 15, and 18 months. Data were analyzed for each time-point and results will be discussed in this report in relation to each specific aim. The sample is primarily middle-aged (M = 52 years; R = 27-83 years), European American (72.6%), has at least some college education (76.5%), and is married (64.2%). Approximately one-half (51.5%) of the sample reported that they were post-menopausal at diagnosis with 48.5% pre-menopausal. Of the women who were pre-menopausal prior to diagnosis, approximately (10%) reported that they were experiencing hot flashes at the 12 month time-point and these younger women reported higher levels of distress related to hot flashes than those women who were postmenopausal and already experiencing hot flashes. Of women currently experiencing hot flashes, 40.7% report at baseline, having used HRT and 26.8% used exercise to control hot flashes. The 12-month data indicates that 26.5% of the entire sample who are experiencing hot flashes, tried or are using some form of HRT to control hot flashes with exercise still the most frequently used approach to manage hot flashes with 44.2% of sample currently exercising.

15. SUBJECT TERMS
Breast Cancer, Hot Flashes, Quality of Life, CAM

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a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
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Introduction

This project is an individual training grant in breast cancer. The project involved focused mentorship and training in all aspects of breast cancer care and research, including psychosocial and quality of life issues. The training program outlined in the grant focused on three main areas coordinated to facilitate development as an independent nurse researcher and focused on broad based quality of life (QOL) and survivorship issues in women with breast cancer. The training consists of: **1)** development of research skills in behavioral oncology and epidemiology; **2)** mentored training in psychosocial research methods and design, and the psychosocial and physiological aspects of breast cancer and its treatment; and **3)** opportunities for experience working with mentors on current research projects and in the development of new research proposals.

The research study segment of this grant is a sub-study within an ongoing project evaluating all new breast cancer patients in the Rowan Breast Center at the UPCC for emotional distress, physical and social functioning, and QOL. Women are recruited at diagnosis and baseline measures are taken. These are repeated at 3 months after treatment began and the use of medical and complementary and alternative (CAM) interventions for hot flashes, hot flash intensity/frequency, emotional distress, physical and social functioning, and QOL are examined. After baseline measures are collected, subjects are followed across 6 month, 9 month, 12 months, 15 month, and 18-month assessment periods. IRB approval was granted by the DOD for this Hot Flash study in 12/04 and although recruitment is closed, data collection is continuing on subjects participating in the study until data is gathered for each time-point.

The literature demonstrates that menopausal-type symptoms are a common problem for breast cancer survivors with 50% or more reporting symptoms that include hot flashes[1]. Women who experience a rapid change in menopausal status from chemically-induced ovarian failure are at greater risk for severe menopausal-type symptoms[2,3]. Hot flashes are the most common complaint among peri-menopausal and post-menopausal healthy women in the population[4,5] and they are significantly more frequent and more severe in breast cancer patients than in the general population of women[6,7]. In addition, hot flashes are reported to interfere with QOL among breast cancer survivors, especially those who experience chemically-induced ovarian failure[4,5, 8,9]. Breast cancer survivors use a variety of pharmacologic and non-pharmacologic approaches to treat hot flashes and improve QOL. There is little research that accurately identifies the wide range of modalities used by breast cancer survivors and there is no consensus regarding the use of any specific modality for the treatment of hot flashes or the impact of hot flashes on QOL.

Body

This project received notice of award on December 4, 2002 and notification of final approval on July 3, 2003 stating that the grant contract was signed and scheduled to begin on July 21, 2003. Preparation for training and research began immediately after the final notification. Key Research Accomplishments, and Education and Career Development Activities including publications and presentations are outlined in the following sections. These items are in accordance with activities described and outlined original proposal and Statement of Work.

Key Accomplishments

1. Specific Aims: The specific aims of this project are:

a. to examine longitudinally the frequency/intensity of hot flashes reported by breast cancer patients experiencing chemically induced menopause compared to breast cancer patients who are menopausal prior to treatment

Approximately one-half (51.5%) of the sample reported that they were post-menopausal at diagnosis with 48.5% reporting that they were pre-menopausal.

Time Points	**Pre-menopausal women experiencing menopausal symptoms**
Baseline	0%
3 months	2.9%
6 months	9.4%
9 months	22.5%
12 months	20.9%
15 months	18.5%
18 months	15.1%

Data collection continues and the data for the 12 month time point is most complete with 20.9% of subjects who were pre-menopausal prior to treatment reporting that they are menopausal at the 12 month time point (Appendix A.)

Patients were questioned regarding the overall severity of their hot flashes and how bothered they are by their hot flashes. There are no significant differences in frequency/intensity of hot flashes reported by breast cancer patients experiencing chemically induced menopause compared to breast cancer patients who were menopausal prior to treatment, at any of the time-points.

b. to examine longitudinally the quality of life (QOL) of breast cancer patients experiencing chemically induced menopause compared to breast cancer patients who are menopausal prior to treatment

QOL was measured at each time-point and significant differences were noted between patients experiencing chemically induced menopause and breast cancer patients who were menopausal prior to treatment (sig=.001) at the 12 month time-point, with younger women who experienced chemically-induced menopause reporting more distress and a breast cancer related decreased QOL (Appendix B.).

c. to determine the association between hot flashes and QOL among breast cancer patients experiencing chemically induced menopause compared to breast cancer patients who are menopausal prior to treatment

Data collection continues and data gathered thus far indicates that patients experiencing chemically induced menopause, a generally younger population than patients who were menopausal prior to treatment, report more distress associated with hot flashes and a poorer QOL at the 12 month time point.

d. to develop a taxonomy of medical, and complementary and alternative medicine (CAM) treatments for hot flashes used by breast cancer patients

Study subjects were questioned regarding the use of a variety of CAM treatment for hot flashes and very few breast cancer patients use any CAM treatments at any time-points (Appendix C for complete data).

e. to determine if changes in hot flash intensity/frequency relate to changes in QOL among breast cancer patients, and if this is mediated by menopause status prior to treatment

There is no evidence that menopausal status prior to treatment mediates any changes in QOL at any of the time-points. Data collection continues and it has become evident that after patients complete treatment the number of questionnaire response decreases. Efforts continue to contact study participants and complete questionnaires via telephone interviews.

Reportable Outcomes

- Biweekly meetings with mentors as well as Dr. Steven Palmer, a behavioral psychologist, who is an additional mentor, to discuss the research project, ongoing training, and other related projects, current literature, and strategies for future work, presentations, and publications.
- Patient recruitment for the Hot Flash research project proposed as part of my training began after DOD IRB approval was granted in 1/05. Total subjects recruited are 196. The investigator works very closely with Dr. Palmer, the coordinator of the parent study who also oversees data collection for the Hot Flash study.
- Biweekly research meetings with breast research project team including Drs. Coyne and Palmer as well as research assistant, Alison Taggi. Review progress to date of parent and Hot Flash studies as well as procedures and preliminary data analysis. Discuss ideas for new projects.
- Data analysis will be ongoing over the next year in order to gather complete data on all subjects at every time point.
- Attend case conferences (bimonthly), breast clinical trial meetings (monthly), and journal clubs (monthly) in the Rowan Breast Center 2001-present.
- Attended a review of Breast Cancer Presentations from the May 2006 ASCO meeting that was held in the Rowan Breast Center at the University of Pennsylvania.
- Invited speaker at the 2006 ASCO meeting in Atlanta, GA, May 2006.

Continue as the Oncology Nursing Society's Research Agenda Panel content area leader for research in survivorship and late effects, revising the 2003-2007 Research Agenda. Meeting February 2007.

Society of Clinical Oncology (ASCO) Survivorship Expert Panel for the development of guidelines for long-term medical care of adult cancer survivors. First meeting, January 26, 2005.

American Society of Breast Disease (ASBD) Annual Meeting, Symposium Presentation, " The Advanced Practice Nurse in the Survivors' Clinic." April 15, 2005.

Journal Articles:

DeMille D, Deming P, Lupinacci P, Jacobs LA. (2006). The effects of the neutropenic diet in an outpatient setting: a pilot study. *Oncology Nursing Forum*, 33, 2:337-343.

Giarelli E, Jacobs LA. (2005). Modifying Cancer Risk Factors: The Gene-Environment Interaction. *Seminars in Oncology Nursing*, 21, 4:271-277.

Zoltick BH, Jacobs LA, Vaughn DJ. (2005). Cardiovascular risk in testicular cancer survivors treated with chemotherapy: incidence, significance, and practice implications. *Oncology Nursing Forum*, 32, 5:1005-1110.

Jacobs L A, Giarelli E. (2004). A model of survivorship in genetic cancer care. *Seminars in Oncology Nursing. 20*, 3:196-202.

Jacobs L A, Scarpa R, Lester J, Smith J. (2004). Oncology nursing as a specialty: The education, scope, and standards for advanced practice nursing in oncology.
Oncology Nursing Forum. 31, 3: 507-509.

Posters:
Palmer, S., Carver, J., Jacobs, L. A., Schmitz, K., Fung, C., Mohler, E., Vaughn, D. American Society of Clinical Oncologists (ASCO) 2006 Annual Meeting. Poster Session. "Assessment of Coronary Heart Disease Risk in Testicular Cancer Survivors." June2-6, 2006.

Jacobs, L.A., Palmer, S., Matthews, G., Robertson, K., Meadows, A.T., Vaughn, D. J. American Society of Clinical Oncologists (ASCO) 2004 Annual Meeting. Poster Discussion. "Late Treatment Effects, Health Behavior, and Quality of Life (QOL) in Testicular Cancer (TC) Survivors." June 5-8, 2004

Jacobs, L. A., DeMichele, A., Shapiro, P. J., Coyne, J. C., Palmer, S. C. Era of Hope 2005 Department of Defense Breast Cancer research Program Meeting, Poster Presentation. "Hot Flashes and Quality of Life among Breast Cancer Patients." June 8-14, 2005.

Alton, J., Jacobs, L.A., Fox, K., Schuchter, L., Domcheck, S., Glick, J., Meadows, A., DeMichele, A. San Antonio Breast Cancer Symposium. Poster Session. "Chemotherapy-related amenorrhea (CRA) in breast cancer survivors: Impact of taxanes on ovarian function." December 2004.

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Jacobs, L.A., Hobbie, W., & Moore, I. (2005). Late effects of cancer treatment. In C. Yarbro, M. Goodman, & M. Frogge, (Eds.), *Cancer Nursing: Principles and Practice, 6th ed*. MA: Jones and Bartlett.

Conclusions
This training grant has concluded. A number of related projects are in the planning phase and the investigator is participating in a number of ongoing projects in numerous areas of cancer survivorship with breast cancer patients as well as survivors of testicular cancer, Hodgkins and non-Hodgkins Lymphoma, and adult survivors of childhood cancer. This training grant has provided the investigator the opportunity to grow as an independent researcher and participate in many valuable experiences. During the period of this training grant, Dr. Jacobs was made

Director of the first adult cancer survivorship program in the country at the Abramson Cancer Center of the University of Pennsylvania. In addition, Dr. Jacobs was invited to apply to the Lance Armstrong Foundation (LAF) for a LIVE**STRONG**™ Survivorship Center of Excellence program grant. This program grant was funded by the LAF on 1/1/07 and will allow Dr. Jacobs to continue her clinical and research focused efforts with cancer survivors (Appendix D. Agenda from last survivorship program team meeting that outlines many ongoing projects and activities.)

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Appendices

Appendix A

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Meno_Stat_12

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Postmenopausal	85	43.4	63.4	63.4
	Remain Premenopasual	21	10.7	15.7	79.1
	Become Menopausal	28	14.3	20.9	100.0
	Total	134	68.4	100.0	
Missing	System	62	31.6		
Total		196	100.0		

Appendix B.

ANOVA

Oneway QoL 12 Month

		Sum of Squares	df	Mean Square	F	Sig.
pwb_12	Between Groups	11.085	1	11.085	.890	.348
	Within Groups	1096.496	88	12.460		
	Total	1107.581	89			
sfwb_12	Between Groups	97.024	1	97.024	3.378	.069
	Within Groups	2527.782	88	28.725		
	Total	2624.807	89			
ewb_12	Between Groups	42.670	1	42.670	2.878	.093
	Within Groups	1304.639	88	14.825		
	Total	1347.309	89			
fwb_12	Between Groups	1.348	1	1.348	.046	.831
	Within Groups	2590.607	88	29.439		
	Total	2591.956	89			
brca_12	**Between Groups**	**373.394**	**1**	**373.394**	**11.339**	**.001**
	Within Groups	**2897.777**	**88**	**32.929**		
	Total	**3271.170**	**89**			
fact12_g	Between Groups	435.677	1	435.677	2.098	.151
	Within Groups	18277.540	88	207.699		
	Total	18713.217	89			
total_12	Between Groups	1615.741	1	1615.741	4.592	.035
	Within Groups	30965.848	88	351.885		
	Total	32581.589	89			

Appendix C.

Frequency Table Baseline

Using hormone replacement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	59	30.1	100.0	100.0
Missing	System	137	69.9		
Total		196	100.0		

Tried hormone replacement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	35	17.9	59.3	59.3
	Checked	24	12.2	40.7	100.0
	Total	59	30.1	100.0	
Missing	System	137	69.9		
Total		196	100.0		

Using non-hormone prescr meds

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	57	29.1	98.3	98.3
	Checked	1	.5	1.7	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Tried non-hormone prescr meds

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	56	28.6	98.2	98.2
	Checked	1	.5	1.8	100.0
	Total	57	29.1	100.0	
Missing	System	139	70.9		
Total		196	100.0		

Using vitamins

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	47	24.0	81.0	81.0
	Checked	11	5.6	19.0	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Tried vitamins

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	47	24.0	79.7	79.7
	Checked	12	6.1	20.3	100.0
	Total	59	30.1	100.0	
Missing	System	137	69.9		
Total		196	100.0		

Using herbs

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	55	28.1	94.8	94.8
	Checked	3	1.5	5.2	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Tried herbs

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	49	25.0	84.5	84.5
	Checked	9	4.6	15.5	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Using diet

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	51	26.0	87.9	87.9
	Checked	7	3.6	12.1	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Tried diet

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	46	23.5	80.7	80.7
	Checked	11	5.6	19.3	100.0
	Total	57	29.1	100.0	
Missing	System	139	70.9		
Total		196	100.0		

Using exercise

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	42	21.4	71.2	71.2
	Checked	17	8.7	28.8	100.0
	Total	59	30.1	100.0	
Missing	System	137	69.9		
Total		196	100.0		

Tried exercise

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	41	20.9	73.2	73.2
	Checked	15	7.7	26.8	100.0
	Total	56	28.6	100.0	
Missing	System	140	71.4		
Total		196	100.0		

Using behavioral methods

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	54	27.6	93.1	93.1
	Checked	4	2.0	6.9	100.0
	Total	58	29.6	100.0	
Missing	System	138	70.4		
Total		196	100.0		

Tried behavioral methods

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	53	27.0	93.0	93.0
	Checked	4	2.0	7.0	100.0
	Total	57	29.1	100.0	
Missing	System	139	70.9		
Total		196	100.0		

Using acupuncture

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	58	29.6	100.0	100.0
Missing	System	138	70.4		
Total		196	100.0		

Tried acupuncture

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	57	29.1	100.0	100.0
Missing	System	139	70.9		
Total		196	100.0		

Using massage

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	56	28.6	94.9	94.9
	Checked	3	1.5	5.1	100.0
	Total	59	30.1	100.0	
Missing	System	137	69.9		
Total		196	100.0		

Tried massage

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	51	26.0	91.1	91.1
	Checked	5	2.6	8.9	100.0
	Total	56	28.6	100.0	
Missing	System	140	71.4		
Total		196	100.0		

Using other

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	37	18.9	97.4	97.4
	Checked	1	.5	2.6	100.0
	Total	38	19.4	100.0	
Missing	System	158	80.6		
Total		196	100.0		

Tried other

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Checked	36	18.4	100.0	100.0
Missing	System	160	81.6		
Total		196	100.0		

Appendix D.
Sample-Penn Survivorship program agenda

University of Pennsylvania Cancer Center
Living Well After Cancer (LWAC) Program
November 20, 2006

Agenda/Summary

Meeting Schedule: Third Monday of **every other month** 12noon in the 702 PT conference room. Please mark your calendars: January 15th, etc.

1. Reports/Planning:
    a. LIVE**STRONG**™ Survivorship Center of Excellence Network
        i. Site Visit- 09/28/2006
        ii. Follow-up Letter 10/25/2006-Attached
            1. Contract deadline 12/15/2006
        iii. Network Meeting-November 6-7, 2006, Austin Texas
            1. Biannual
                a. April 10-11, 2007
                b. October 25-26, 2007
            2. Center Director Reports (attached)
                a. Clinical
                    i. Populations
                b. Research
                    i. Databases
                    ii. Tools
            3. See minutes (attached)
        iv. Timeline for program goals-Penn and Network
            1. Project teams-develop timeline for grant activities
                a. Date for meeting 12/06-Jo
            2. Treatment summaries
                a. Network subcommittee-4 cancer sites (breast, colorectal, prostate, and Hodgkin Lymphoma)-draft by January 2007
                b. Development phase-ASCO-Patti Ganz
                c. Sample from MSKCC (attached)
                d. Process at Penn
            3. Personal Health History
                a. Tool developed/validated at Fred Hutchinson Cancer Research Center
                    i. Requested for review
                    ii. Pilot at Penn
                    iii. Use by Network Centers
            4. TC Database update-Jo

a. Mtg. Tuesday 11/28/06 9-11am
    i. Strategy to present to the IT group outlining what it is we want, who should have access, etc.
5. BC survivors revised protocol-11/06 submission-Steve, Jo
    a. BCDB update-Lauren
6. Lymphoma survivors protocol
7. BMT survivors protocol

8. Transition program
    a. Research protocols/ideas
        i. Exercise Testing Pilot-Katie
            1. CV Risk-further studies-exploratory
                a. Cancer Center Grant
                b. AstraZeneca Education Grant
        ii. CHOP Behavioral Science-Anne Kazak/Brandy Werba-Steve
            1. Examination of barriers and facilitators to the transition from pediatric survivorship care to adult care
    b. Vision
    c. Expansion
9. Community Based Centers-Cindy Stern
    a. Planning meeting 1/07
10. External advisory board meeting
    a. Schedule for 2/07
    b. Dates

2. Approved/open projects & planning for new projects:
    a. Priority-Fall 2006
        i. The Breast Cancer Survivors' Protocol-Revisions & submission
            1. PI-Steve
            2. Co-I: Linda, Carrie, Angie
        ii. BMT Survivors' Protocol development
        iii. Database
            1. Status-Angie, Lauren, Jo
    b. Testicular
        i. Genetic study-Jo
            1. Ongoing recruitment
        ii. R21-Study closed
            1. Progress Report-Jo
                a. Completing data
        iii. R01- Endothelial Dysfunction in TC Survivors
            1. to be submitted Spring 2007-David, Steve

c. Adult Survivors of Childhood Cancer (proposed projects outlined earlier)

3. Reports from consultation services/presentations & miscellaneous projects
   a. Cancer Survivorship: Embracing the Future Third Biennial Cancer Survivorship Research Conference October 4-6, 2006 Bethesda North Marriott Hotel-Linda, David
   b. Grand Rounds in Population Science Seminar Series (GRIPS) at Moffitt Cancer Center, Cancer Center Prevention and Control Division, December 6-7, 2006-Linda
   c. 9th National Conference on Cancer Nursing Research February 8-10, 2007
      i. Closing Session-February 10, 2007
      ii. Pre-Conference Research Agenda-Team leader, Survivorship-February 7, 2007
   d. Visitors from Austin Children's Hospital-Program recently funded by the LAF
      i. Christina Allegretti callegretti@sfcaustin.com and Lori Boucher lboucher@sfcaustin.com
      ii. Goals, dates to follow
   e. Program Brochures
      i. Adult Survivors Program
      ii. Adult Survivors of Childhood Cancer Program